



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/597,974

06/12/2007

Jean-Claude Amelia

8279.88901

8764

22242 7590 10/01/2010
FITCH EVEN TABIN & FLANNERY
120 SOUTH LASALLE STREET
SUITE 1600
CHICAGO, IL 60603-3406

EXAMINER

LOGIE, MICHAEL J

ART UNIT

PAPER NUMBER

2881

MAIL DATE

DELIVERY MODE

10/01/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/597,974	Applicant(s) AMELIA ET AL.	
	Examiner MICHAEL J. LOGIE	Art Unit 2881	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,7-14,17 and 20-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,7-14,17 and 20-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>04/27/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 27 April 2010 has been entered.

Response to Amendment

An "Amendment" was received on 27 April 2010, in response to Office Action of 27 January 2010. Claims 1 and 17 have been amended. Claims 21-40 have been newly added. Claims 1, 3-5, 7-14, 17, and 20-40 are now pending.

Response to Arguments

Applicant's arguments with respect to claims 1, 3-5, 7-14, 17, 20 and 21-40 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Art Unit: 2881

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 9-11, 13, 17, 20-22, 27-32, 37, 38 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over BE 1011263 A6 (translation submitted by applicant on 12/16/2009)(herein '263) and further in view of Zeisler et al. (Zeisler et al., "A water-cooled spherical niobium target for the production of [^{18}F]fluoride", Applied Radiation and Isotopes 53 (2000) 449-453)(copy of publication submitted herewith).

In regards to claim 1, '263 teaches an irradiation cell (fig. 1) for producing a radioisotope of interest through the irradiation of a target material by a particle beam (page 2, lines 8-12), comprising a target body (page 5, line 14), a removable metallic insert (fig. 1, 8, figure 2 shows an exploded view thus removable, further an insert is removable by definition) comprising a cavity designed to house the target material (page 4, lines 10-11 and page 4, lines 28-30 teach the cavity holds the target and the cavity is made with an insert) and closed by an irradiation window (page 4, lines 10-11 teach a charged particle beam sent to a target within a cavity, thus the cavity must inherently be closed by an irradiation window to allow the charged particle beam access to the cavity) and configured to be inserted in and removed from the target body (where an insert can be inserted, it can be removed from the body, thus the limitation is interpreted to be met), wherein the removable metallic insert comprises at least two separate metallic parts (fig. 1, the insert part forming the target cavity is the first part and the insert part forming the channel 2 is the second part, page 5, lines 12 teaches "insert parts". Page 4 teaches the insert is made of titanium or silver. Also note: "It is not invention to make integral, parts that have formerly been distinct, or *to separate two*

Art Unit: 2881

elements that formerly were integral; unifying of structural elements of apparatus to simplify it and to achieve economy of working parts is usually but routine accomplishment of practical designer " see 64 USPQ 77 THE CLEVELAND PUNCH & SHEAR WORKS CO. v. E. W. BLISS COMPANY et al.; SAME v. MARQUETTE TOOL & MANUFACTURING CO.; E. W. BLISS COMPANY et al. v. THE CLEVELAND PUNCH & SHEAR WORKS CO. Circuit Court of Appeals, Sixth Circuit Nos. 9748-5 Decided December 7, 1944), being composed of at least a first part and a second part (the insert part forming the target cavity is the first part and the insert part forming the channel 2 is the second part,), the first part having an elongated cavity that is longer in a direction parallel to the particle beam that irradiates the target than in a direction perpendicular to the particle beam (as seen in figure 1), and the second part surrounding the first part and forming a channel for guiding a cooling medium (also seen in figure 1 wherein the second part forms the cooling channel 2, see page 4, lines 23-30 and page 5, lines 7-9).

'263 differs from the claimed invention by not teaching a different material of one of the insert parts.

However, Zeisler et al. teach a different material for the target chamber (i.e. niobium, see figure 2 on page 451 element 5 is made of niobium and is equivalent to the cavity 1 of insert 8 of '263).

Zeisler et al. modifies '263 by providing the cavity part of the insert to be made of niobium instead of silver or titanium.

Since both inventions are directed towards target chambers, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the niobium cavity of Zeisler et al. in as the material for the target chamber of '263 because "results indicate that niobium is an excellent material for the construction of target chambers for [^{18}F] fluoride production. In addition to its favorable chemical and mechanical characteristics this target is easy to maintain due to low activation by the relatively short-lived $^{93\text{m}}\text{Mo}$ " (page 452, first column last paragraph before the acknowledgements section).

In regards to claims 3, 22 and 32, '263 teaches wherein said cell further comprises a supply means for a cooling medium (fig. 1, 10) and in connection with the supply means, a diffuser device surrounding the first part (fig. 1, 3), the diffuser device being configured to guide the cooling medium around the first part (page 4, lines 19-27), and wherein the second part surrounds both the first part and the diffuser device in a manner to form a return path for the cooling medium between the diffuser device and the second part (as seen in figure 1, inlet 10, outlet 20, channel 2, cavity 1).

In regards to claims 9, 27 and 37, '263 teaches wherein the first part comprises a flat, circular and ring-shaped portion having an inner circular edge and an outer circular edge, a cylindrical portion rising perpendicularly from the inner circular edge of the flat portion, and a hemispherical portion being on top of the cylindrical portion, the cavity being formed inside the cylindrical and hemispherical portions (as seen in figure 1).

Art Unit: 2881

In regards to claims 10 and 28, '263 differs from the claimed invention by not disclosing wherein the cylindrical portion has a wall thickness comprised between .3 and .7 mm.

However, Zeisler et al. teach wherein the cylindrical portion has a wall thickness comprised between .3 and .7 mm (page 450, section 4 shows an equation wherein the wall thickness is a variable, as such .3 to .7 mm is a possible range of wall thicknesses).

Zeisler et al. modifies '263 by providing the cavity part of the insert to be made of niobium instead of silver or titanium.

Since both inventions are directed towards target chambers, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the niobium cavity of Zeisler et al. in as the material for the target chamber of '263 because "results indicate that niobium is an excellent material for the construction of target chambers for [^{18}F] fluoride production. In addition to its favorable chemical and mechanical characteristics this target is easy to maintain due to low activation by the relatively short-lived $^{93\text{m}}\text{Mo}$.

In regards to claims 11 and 29, '263 teaches wherein the second part has the form of a hollow cylinder having two flat sides essentially perpendicular to a cylindrical side, the cylinder being connected by one flat side against the flat portion of the first part (as seen in figure 1 and discussed in citations herein above).

Claim 13 and 38 is taught as in the discussion above in claim 1.

In regards to claim 17, '263 teaches filling the cavity volume of the irradiation cell with about 50% of target material before starting irradiation (because the cavity container can be filled, it is capable of being filled to 50% of its volume).

In regards to claims 20 and 40, '263 teaches wherein the cell further comprises a supply tube for a cooling medium and, in connection with the supply tube, a diffuser device mounted on one end of the supply tube (fig. 1, supply tube 10 and diffuser 3), the diffuser device surrounding the first part, the diffuser element being configured to guide the cooling medium around the first part (page 4, lines 23-27), and wherein the second part surrounds both the first part and the diffuser element in a manner to form a return path for the cooling medium between the diffuser element and the second part (see figure 1).

In regards to claim 21, '263 teaches an irradiation cell (fig. 1) for producing a radioisotope of interest through the irradiation of a target material by a particle beam (page 2, lines 8-12), comprising a target body (page 5, line 14), a removable metallic insert (fig. 1, 8, figure 2 shows an exploded view thus removable, further an insert is removable by definition) comprising a cavity designed to house the target material (page 4, lines 10-11 and page 4, lines 28-30 teach the cavity holds the target and the cavity is made with an insert) and closed by an irradiation window (page 4, lines 10-11 teach a charged particle beam sent to a target within a cavity, thus the cavity must inherently be closed by an irradiation window to allow the charged particle beam access to the cavity) and configured to be inserted in and removed from the target body (where an insert can be inserted, it can be removed from the body, thus the limitation is

Art Unit: 2881

interpreted to be met), wherein the removable metallic insert comprises at least two separate metallic parts (fig. 1, the insert part forming the target cavity is the first part and the insert part forming the channel 2 is the second part, page 5, lines 12 teaches "insert parts". Page 4 teaches the insert is made of titanium or silver. Also note: "It is not invention to make integral, parts that have formerly been distinct, or *to separate two elements that formerly were integral*; unifying of structural elements of apparatus to simplify it and to achieve economy of working parts is usually but routine accomplishment of practical designer " see 64 USPQ 77 THE CLEVELAND PUNCH & SHEAR WORKS CO. v. E. W. BLISS COMPANY et al.; SAME v. MARQUETTE TOOL & MANUFACTURING CO.; E. W . BLISS COMPANY et al. v. THE CLEVELAND PUNCH & SHEAR WORKS CO. Circuit Court of Appeals, Sixth Circuit Nos. 9748-5 Decided December 7, 1944), being composed of at least a first part and a second part (the insert part forming the target cavity is the first part and the insert part forming the channel 2 is the second part), the first part forming a cavity that is elongate in a direction parallel to the particle beam that irradiates the target (as seen in figure 1), and the second part being a generally cylindrical hollow member comprising a material selected from the group consisting of stainless steel, silver, and titanium, with the second part disposed around at least a portion of the elongate cavity of the first part and the first and second parts forming a channel which guides a cooling medium (also seen in figure 1 wherein the second part forms the cooling channel 2, see page 4, lines 23-30 (silver or titanium material of second part) and page 5, lines 7-9).

'263 differ from the claimed invention by not teaching the first part comprising a material selected from the group consisting of niobium and tantalum.

However, Zeisler et al. teach a different material for the target chamber (i.e. niobium, see figure 2 on page 451 element 5 is made of niobium and is equivalent to the cavity 1 of insert 8 of '263).

Zeisler et al. modifies '263 by providing the cavity part of the insert to be made of niobium instead of silver or titanium.

Since both inventions are directed towards target chambers, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the niobium cavity of Zeisler et al. in as the material for the target chamber of '263 because "results indicate that niobium is an excellent material for the construction of target chambers for [^{18}F] fluoride production. In addition to its favorable chemical and mechanical characteristics this target is easy to maintain due to low activation by the relatively short-lived $^{93\text{m}}\text{Mo}$ " (page 452, first column last paragraph before the acknowledgements section).

Claim 31 is taught as above in claim 1, wherein '263 teaches the additional limitation of a channel configured to guide a cooling medium in a direction parallel to the direction of the beam and perpendicular to the direction of the beam so that the cooling medium surround the cavity (fluid surround the walls 4 of the cavity 1 as discussed on page 5, lines 3-6 and because the cavity has a hemispherical shape (fig. 1) the fluid is guided by channel 2 in a direction both parallel and perpendicular to the irradiating beam).

Claims 4, 5, 7, 8, 12, 23-26, 30 and 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over BE 1011263 A6 (translation submitted by applicant on 12/16/2009)(herein '263) and Zeisler et al. (Zeisler et al., "A water-cooled spherical niobium target for the production of [^{18}F]fluoride", Applied Radiation and Isotopes 53 (2000) 449-453)(copy of publication submitted herewith) and further in view of Schlyer et al. (USPN 5,917,874).

In regards to claims 4, 5, 7, 8, 12, 23-26 and 33-36 the combined invention fails to teach coupling of the two parts by o-rings gold foil, bolts, and welding.

Schyler et al. teaches coupling by bolts (col. 4, lines 18-22). Although Schlyer et al. only describes coupling by bolts, fixing means such as gold foil, bolts and welding are commonly used in assembling devices and integration is part of the common knowledge of a skilled person. Thus having such fixing means would have been obvious to one of ordinary skill in the art because the substitution of one known element for another would have yielded predictable results.

Schyler modifies the combined invention by providing fixing means between two parts.

Since both the combined invention and Schyler teach irradiating target chambers, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the fixing means of Schyler in the combined device because the simple substitution of one known element for another (i.e. integral parts for

Art Unit: 2881

two separate parts and joining them therein) would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Claims 14 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over BE 1011263 A6 (translation submitted by applicant on 12/16/2009) (herein '263) and Zeisler et al. (Zeisler et al., "A water-cooled spherical niobium target for the production of [^{18}F] fluoride", Applied Radiation and Isotopes 53 (2000) 449-453) (copy of publication submitted herewith) and further in view of Zeisler et al. (US pgPub 2005/0201504).

In regards to claims 14 and 39, the combined invention differs from the claimed invention by not disclosing the second part is made of stainless steel.

Zeisler et al. teach a second part made of stainless steel ([0025]).

Zeisler modifies the combined invention by providing fixing means between two parts.

Since both the combined invention and Zeisler teach irradiating target chambers, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the fixing means of Zeisler in the combined device because the simple substitution of one known element for another (titanium for stainless steel) would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Pertinent prior art is closely related art that individually or in combination could be considered grounds for rejection. See references cited for a listing of the pertinent prior art found and the prior art found.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL J. LOGIE whose telephone number is (571)270-1616. The examiner can normally be reached on 8:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Kim can be reached on 571-272-2293. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. J. L./
Examiner, Art Unit 2881

Application/Control Number: 10/597,974

Page 13

Art Unit: 2881

/ROBERT KIM/

Supervisory Patent Examiner, Art Unit 2881